APR - 3 2008

K080789
p1/3

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of AAMI SP10:2002 and 21 CFR § 870-1130.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

Name: SEJOY ELECTRONICS &. INSTRUMENTS CO., LTD
Add.: 4th Floor, B2 Building, Feng-Tan-Lu Industrial Zone, West Lake District, Hangzhou, P. R. China

2. **Name of the Device:**

Proprietary Name: Blood Pressure Monitor Model BP Series
Including: Arm-Type Fully Automatic Digital Blood Pressure Monitor BP-102
Arm-Type Fully Automatic Digital Blood Pressure Monitor BP-103
Wrist-Type Fully Automatic Digital Blood Pressure Monitor BP-201
Wrist-Type Fully Automatic Digital Blood Pressure Monitor BP-202

Common Name: Noninvasive blood pressure measurement systems
Classification name: Non-invasive blood pressure measurement System
21 CFR 870-1130, Class II, 74-DXN.

3. **Predicate Device Information:**

For submitted devices BP-102 and BP-103:

* Memory Automatic Electronic Blood Pressure Monitor (Model: KD-575)
510(k) number: K042418
Applicant: KODON (TIANJIN) ELECTRONIC&ELECTRICAL APPARATUS CO.
Owner: KODON (TIANJIN) ELECTRONIC&ELECTRICAL APPARATUS CO.

For submitted devices BP-201 and BP-202:

* Memory Wrist Automatic Electronic Blood Pressure Monitor (Model: KD-726)
510(k) number: K030359
Applicant: KODON (TIANJIN) ELECTRONIC&ELECTRICAL APPARATUS CO.
Owner: KODON (TIANJIN) ELECTRONIC&ELECTRICAL APPARATUS CO.

4. **Device Description:**

Based on oscillometric and silicon integrate pressure sensor technology, blood pressure monitor model BP series (BP-102, BP-103, BP-201, BP-202) are used to monitor systolic, diastolic blood pressure and pulse rate which will be shown on the LCD.

BP-102 and BP-103 are the arm-type Blood pressure monitors, which can measure the systolic, diastolic pressure and pulse rate at upper-arm. BP-102 could measure the systolic, diastolic pressure and pulse, and it could display last measurement. Base on the BP-102, the BP-103 is designed as a function expanding product. which have 120 times memories with date and time and the date and time can be reset too.

BP-201 and BP-202 are the wrist-type Blood pressure monitors, which can measure the blood pressure and pulse rate at wrist. The devices are reusable for clinical and home use. BP-201 could measure the systolic, diastolic pressure and pulse, and it could display last measurement. Base on the BP-201, the BP-202 is designed as a function expanding product, which have 120 times memories with date and time and the date and time can be reset

5. **Intended Use:**

Blood pressure monitor model BP series are designed to measure the systolic, diastolic pressure and pulse rate of people by using a non-invasive technique. which is a well-known technique in the market called the "oscillometric method".
BP-102 and BP-103 are the arm-type Blood Pressure Monitors, which can measure the systolic, diastolic pressure and pulse rate at upper-arm, and BP-201 and BP-202 are the wrist-type Blood Pressure Monitors, which can measure the systolic. diastolic pressure and pulse rate at wrist. and the devices are reusable for clinical and home use.

6. **Comparison to Predicate Devices:**

The device models BP-102, BP-103 are similar in design and intended use to the KODON Memory Automatic Electronic Blood Pressure Monitor (Model: KD-575) Differing mostly in physical dimensions.
The device models BP-201, BP-202 are similar in design and intended use to the KODON Memory Wrist Automatic Electronic Blood Pressure Monitor (Model: KD-726). Differing is mostly in physical dimensions and appearance.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards including ANSI/AAMI SP10: 2002 as well as IEC60601-1 and IEC60601-1-2, EN 1060-1:1995 and EN1060-3:1997 requirement.
Guidance documents include the "FDA Non-invasive Blood Pressure (NIBP) Monitor Guidance" and "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

Non-clinical Tests:

Electromagnetic Compatibility Test according to EN60601-1-2:2001
General Safety Provisions Test according to EN60601: 2001
Performance Test according to EN1060-1:1995 & EN1060-3:1997
Performance Test according to ANSI/AAMI SP10:2002
The test result all meet or exceed the accuracy requirement of the standards.

8. **Discussion of Clinical Tests Performed:**

Clinical tests were performed and complied the accuracy requirements of ANSI/AAMI SP10:2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers"
Controlled human clinical studies were conducted using the Blood Pressure Monitor model BP series. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Sejoy Clinical Test Protocol outline. The results meet or exceed the accuracy requirements of ANSI/AAMI SP10-2002.

9. **Conclusions:**

The Blood Pressure Monitor model BP series, Model BP-102, BP-103 have the same intended use and similar technological characteristics as the Memory Automatic Electronic Blood Pressure Monitor (Model: KD-575). The Model BP-201 and BP-202 have the same intended use and similar technological characteristics as the Memory Wrist Automatic Electronic Blood Pressure Monitor (Model: KD-726). Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Blood Pressure Monitor Model BP Series are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

Sejoy Electronics and Instruments Co., Ltd.
c/o Ms. Laura Danielson
Program Manager
TUV SUD AMERICA, INC.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K080789
Blood Pressure Monitor, Models BP-102, BP-103, BP-201, BP-202
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 18, 2008
Received: March 20, 2008

Dear Ms. Danielson:

This letter corrects our substantially equivalent letter of April 03, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

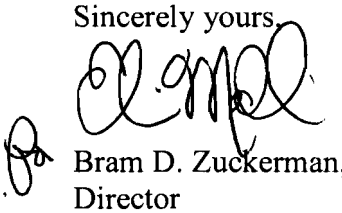
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080789

Indications for Use

510(k) Number (if known):

Device Name: Blood Pressure Monitor Model BP series

Indications For Use:

Blood pressure monitor model BP series are designed to measure the systolic, diastolic pressure and pulse rate of people by using a non-invasive technique, which is a well-known technique in the market called the "oscillometric method".

BP-102 and BP-103 are the arm-type Blood Pressure Monitors, which can measure the systolic, diastolic pressure and pulse rate at upper-arm, and BP-201 and BP-202 are the wrist-type Blood Pressure Monitors, which can measure the systolic, diastolic pressure and pulse rate at wrist, and the devices are reusable for clinical and home use.

Prescription Use_____ **AND/OR** **Over-The-Counter Use** √
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080789